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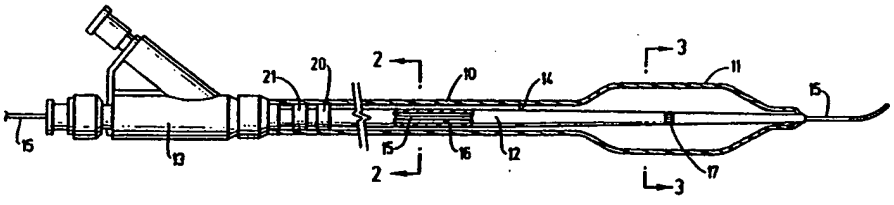

(57) Abstract

The present invention relates to a low friction component formed of a polymer matrix having incorporated within the matrix a lubricous fluid for use in an intravascular catheter, particularly a balloon dilatation catheter. The polymer matrix preferably is a thermoplastic polymer, suitable lubricous fluid and a polysiloxane fluid. Typical components made of this low-friction material include the inner or outer tubular members of fixed-wire and over-the-wire dilatation catheters.

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COMPOSITE MATERIAL HAVING A LUBRICOUS SURFACE FOR CATHETER USE

BACKGROUND OF THE INVENTION

This invention generally relates to intraluminal catheters, such as guiding catheters, and angiographic catheters and balloon dilatation catheters used in percutaneous transluminal coronary angioplasty (PTCA).

PTCA is a widely used procedure for the treatment of coronary heart disease, wherein a balloon dilatation catheter is advanced into the patient's coronary artery and a relatively inelastic balloon on the distal end of the catheter is inflated within the stenotic region of the patient's artery to open up the arterial passageway and increase the blood flow through the artery.

To facilitate the advancement of the dilatation catheter into the patient's coronary artery, a guiding catheter having a preshaped distal tip is

first percutaneously introduced into the cardiovascular system of a patient by the Seldinger technique through the brachial or femoral arteries. The guiding catheter is advanced within the arterial system until the preshaped distal tip of the guiding catheter is disposed within the aorta adjacent the ostium. The guiding catheter is twisted or torqued from the proximal end, which extends out of the patient, to guide the distal tip of the guiding catheter into the ostium of the desired coronary artery. The balloon dilatation catheter may then be advanced through the guiding catheter into the patient's coronary artery until the balloon on the catheter is disposed within the stenotic region of the patient's artery. The balloon is inflated to dilatate the stenosis.

One type of dilatation catheter frequently used in PTCA procedures is an over-the-wire type balloon dilatation catheter, such as the SIMPSON ULTRA LOW PROFILE®, the HARTZLER ACX®, the HARTZLER ACX II®, the PINKERTON .018™ and the ACS TEN™ balloon dilatation catheters sold by the assignee of the present invention, Advanced Cardiovascular Systems, Inc. (ACS). When using an over-the-wire dilatation catheter, a guidewire is usually inserted into an inner lumen of the catheter before it is introduced into the patient's vascular system and then both are introduced into and advanced through the guiding catheter to its distal tip which is seated within the ostium of the desired coronary artery. The guidewire is first advanced out the seated distal tip of the guiding catheter into the desired coronary artery until the distal end of the guidewire extends beyond the lesion to be dilated. The dilatation catheter is then advanced out of the distal tip of the guiding catheter into the

patient's coronary artery, over the previously advanced guidewire, until the balloon on the distal extremity of the dilatation catheter is properly positioned across the lesion to be dilated. Once properly positioned across the stenosis, the balloon is inflated one or more times to a predetermined size with radiopaque liquid at relatively high pressures (*e.g.*, generally 4-12 atmospheres) to dilatate the stenosed region of a diseased artery. After the dilatation the balloon dilatation catheter is removed from the dilated stenosis and increased rates of blood will flow through the dilated region.

Various improvements have been made to intravascular catheters used in angioplasty and other intravascular procedures. Of particular note is a rapid exchange type catheter described and claimed in U.S. Patent 5,040,548 (Yock), U.S. Patent 5,061,273 (Yock), and U.S. Patent 4,748,982 (Horzewski *et al.*), which are incorporated herein in their entirety by reference. The rapid exchange type dilatation catheter has a short guidewire receiving sleeve or inner lumen extending through the flexible distal portion of the catheter which extends out of the guiding catheter into the patient's coronary artery during the angioplasty procedure. The sleeve extends proximally a distance of at least 10 cm and usually not more than about 50 cm from a first guidewire port in the distal end of the catheter to a second guidewire port in the catheter spaced proximally from the inflatable balloon of the catheter. A slit, as described in Horzewski *et al.*, is preferably provided in the catheter wall which extends distally from the second guidewire port, preferably to a location proximal to the proximal end of the inflatable balloon to aid in the removal of the catheter from

the guidewire. The structure of the catheter allows for the rapid exchange of the catheter without the need for the use of an exchange wire or adding a guidewire extension to the proximal end of the guidewire. The design of this catheter has been widely praised by the medical profession and has met with much commercial success in the market place because of its unique design.

A substantial improvement in the rapid exchange type dilatation catheters, such as described above, has recently been made by McInnes *et al.* which is described in copending applications Serial No. 07/476,056, filed February 7, 1990 and Serial No. 07/541,264 filed June 19, 1990, both entitled READILY EXCHANGEABLE PERFUSION DILATATION CATHETER, and which are incorporated herein by reference. In these rapid exchange type dilatation catheters, perfusion ports are provided in the catheter shaft, proximal and distal to the balloon, which are in fluid communication with the guidewire receiving inner lumen to allow blood to perfuse distal to the catheter when the balloon is inflated.

One of the deficiencies noted with over-the- wire dilatation catheters is the difficulty in the ability of the catheter to advance or track over the guidewire when making sharp turns in tortuous anatomy. The tracking characteristics of a catheter is a function of both the pushability and the flexibility of the catheter shaft and the frictional characteristics of the guidewire receiving inner lumen within the catheter. Prior art references refer to the use of inner tubular members formed of lubricous fluoropolymers in over-the-wire

dilatation catheters, but there is no evidence that these catheters have been produced commercially.

Additionally, lubricous coatings have been applied to the surfaces of guiding catheters, dilatation catheters and other intraluminal catheters in order to reduce the friction between the surfaces of these catheters and other components of the catheter systems in which the catheters are employed during the intravascular procedures. Lubricous silicone coatings have been applied to the surfaces of guidewires and of dilatation catheters to likewise reduce the frictional characteristics of these devices. However, the application of these lubricous coatings and linings are for the most part complicated manufacturing processes. Moreover, these coatings and linings may not be very durable and may lose substantial portions of their lubricity during the intraluminal or intravascular procedure.

What has been needed and heretofore unavailable is a durable high strength plastic surface having long lasting lubricity which does not require complicated manufacturing procedures, particularly for use in the guidewire receiving inner lumen of the catheter, to increase the trackability of the catheter. The present invention satisfies this and other needs.

SUMMARY OF THE INVENTION

The present invention is directed to an improved composite plastic

material having a very durable lubricous surface and particularly to tubular products for intraluminal catheter procedures within a human patient made from such composite materials.

The material of the invention generally includes a biocompatible polymer matrix having a lubricous fluid such as silicone oil incorporated within the matrix.

The polymer matrix can be formed of thermoplastic or thermosetting materials, or mixtures thereof. However, thermoplastic materials, particularly thermoplastic polymers having substantial crystallinity such as polyethylene, are preferred when the final product has a tubular shape because thermoplastic resins can be more easily extruded or otherwise formed in a conventional fashion. When the lubricous oil is well dispersed within the polymer matrix the extrusion pressure or other forces needed to form the product are significantly lowered and there is much better dimensional control during the extrusion process than the same plastic materials without the lubricous matter incorporated therein. The coefficient of friction of this material typically ranges from about 0.03 to about 0.20.

The tubular products of the invention can be formed into the shafts or inflatable members, *e.g.,* balloons, of intraluminal catheters such as balloon dilatation catheters for angioplasty procedures in a conventional manner. Both the shafts and the balloons exhibit the same improvements in lubricity and

strength with the materials of the invention.

These and other advantages of the invention will become more apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevational view, partially in section of a balloon dilatation catheter embodying features of the invention.

Fig. 2 is a transverse cross-sectional view of the catheter shown in Fig. 1 taken along the lines 2-2.

Fig. 3 is a transverse cross-sectional view of the catheter shown in Fig. 1 taken along the lines 3-3.

DETAILED DESCRIPTION OF THE INVENTION

Figs. 1-3 illustrate a balloon dilatation catheter which embodies features of the invention. The dilatation catheter generally includes an outer tubular member 10, a dilatation balloon 11 on the distal portion of the outer tubular member, an inner member 12 disposed within the outer tubular member

and the balloon and a multi-arm adapter 13 mounted on the proximal ends of the inner and outer tubular members. The distal end of the balloon 11 is sealed about the distal end of the inner tubular member 12 so that injection of inflation fluid under significant pressure through annular lumen 14 to the interior of the balloon will result in the inflation thereof. A guidewire 15 is slidably disposed within the inner lumen 16 of the inner tubular member 12. The distal end of the catheter is provided with a self venting means such as described in U.S. Patent 4,638,805 (Powell).

A radiopaque marker 17 is disposed about the inner tubular member 12 at the mid-point of the balloon 11 to facilitate the fluoroscopic observation thereof during an angioplasty procedure. The brachial marker 20 and femoral marker 21 are provided on the proximal end of the inner tubular member 12.

In accordance with the invention, the inner tubular member 12 is formed of composite material which generally includes a polymer matrix, preferably a readily extrudable thermoplastic polymer, and incorporated within the polymer matrix is a lubricous fluid. The amount of lubricous fluid in the polymer matrix thereof may range from about 0.5 to about 20%, preferably about 2 to about 10%, of the precured mixture thereof. As used herein all percentages are weight percent unless noted otherwise. Up to about 1% of a dispersing agent, such as lecithin, silicone oil, vegetable oil, polyethylene wax or mixtures thereof, may be incorporated into the mixture to facilitate effective

mixing of the lubricous fluid within the polymer resin. A commercially available cooking oil described at least in part in U.S. Patent 4,188,412 and sold under the trademark PAM® by Boyle-Midway Products, Inc., New York, New York, has been found to be particularly suitable.

Particularly suitable lubricous fluids for incorporation into the polymer matrix include silicone oils such as dimethylsiloxane polymers having a viscosity between about 300 and 100,000 centipoise, preferably about 1000 to about 30,000 centipoise.

Suitable polymer materials include thermoplastic and thermosetting polymers or mixtures thereof, although thermoplastic polymer resins are preferred because of their ease in manufacturing tubular and other products by extruding and other types of pressure forming. Polymer materials such as polyethylene, polypropylene, polyvinyl chloride, polyethylene terephthalate, polyesters (*e.g.*, Dacron®), polyamids (*e.g.*, Nylon®), and ionomers (*e.g.*, Surlyn® such as 8020) all sold by E.I. duPont, deNemours & Co., are particularly suitable. Blends of such materials may also be used.

Formation of the products of the invention typically involve intimately mixing the lubricous liquid into the uncured polymer resin which forms the matrix of the cured product. A dispersant may be first mixed with the lubricous fluid to facilitate a more uniform dispersement of the fluid throughout the uncured resin. The dispersant may be advantageously added to the lubricous

fluid as a solution of isopropyl alcohol or other suitable solvent to facilitate the incorporation thereof. The intimate and uniform mixing of the lubricous fluid within the polymer matrix can be very difficult without a dispersant.

The polymer-lubricous fluid mixture is then preferably extruded in a conventional manner into a tubular product having the desired dimensions. After extruding, the tubular product is then cured. If the polymer matrix is a thermoplastic material such as polyethylene, the extruded product may be cross-linked or modified by a conventional radiation treatment with electron beam radiation or gamma radiation or by chemical means such as using a peroxide or other inorganic catalysts. Radiation levels of about 2 to about 150 μrads have been found to be suitable. After curing the tubing may be cut to the desired length depending upon the ultimate end use of the final product.

If the tubular product is to be used to form an inflatable member for an angioplasty catheter, such as element 12 shown in the drawings, the distal portion of the tubular product is disposed within the interior of a hollow mold, which has the desired shape of the inflatable member to be made, and then the interior of the distal portion of the tubular product is subjected to heat and pressurized fluid to expand the distal section within the mold to form the inflatable member of the desired size and shape.

To illustrate a presently preferred embodiment, a 10,000 gram mixture was prepared containing 9,800 grams (98%) of high density polyethylene

(HDPE) and 200 grams of Dow Corning 360 Silicone Oil with a viscosity of 12,500 centipoise. These materials were introduced into a twin screw extruder and compounded together and pelletized to form plastic pellets comprised of 98% HDPE and 2% silicone oil. The pellets were then extruded into a tubular product having nominal inner and outer diameters of about 0.019 inch (0.048 cm) and 0.0255 inch (0.065 cm) respectively, and the extruded tubular member was irradiated with electron beam radiation at a level of about 10 mrads. The tubular member was then cut to length and used in the manufacture of a prototype dilatation catheter as shown in Figures 1 through 3. The tubular member had a coefficient of friction of approximately 0.1. This coefficient of friction was reduced slightly (to approximately 0.09) by subsequent heating in an oven at about 80° C for approximately one hour.

In a second presently preferred embodiment, a 10,000 gram mixture was prepared containing 9,400 grams of HDPE, 400 grams (4%) of polytetrafluoroethylene powder and 200 grams (2%) of Dow Corning 360 silicone oil of viscosity 12,500 centipoise. These materials were then introduced into a twin screw extruded and compounded together to form plastic pellets comprised of 94% HDPE, 4% PTFE and 2% silicone oil. The pellets were extruded into a tubular product having nominal inner and outer diameters of about 0.019 inch (0.048 cm) and 0.0255 inch (0.065 cm), respectively and the extruded tubular member was irradiated with electron beam radiation to a level of about 10 mrads. The tubular member was then cut to length and used in the manufacture of a prototype dilatation catheter as shown in Figures 1-3. The

tubular member had a coefficient of friction of about 0.09.

While the invention has been described herein primarily in terms of an inner tubular member for an over-the-wire type dilatation catheter of concentric design, the composite material of the invention can be utilized in a wide variety intraluminal catheter components. For example, the material can be used to form the outer tubular member in over-the-wire, fixed wire, perfusion and rapid exchange type dilatation catheters. All or a portion of the outer tubular member may be formed of the polymer matrix lubricous fluid composite. The material can also be used to form the inflatable member or balloon of a dilatation catheter. Guidewire receiving inner tubular members such as described in the Yock and Horzewski *et al.* patents, which have been incorporated herein, may be made of the composite material formed of polymer and low friction fluid. Another use is the formation of guiding catheters in which the composite material is used to form at least the inner liner of the catheter to provide the lubricous inner lumen required in this type of intravascular catheter.

While the invention is described herein in terms of certain presently preferred embodiments, those skilled in the art will recognize that various changes and improvements can be made to the present invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

1. An intravascular catheter comprising an elongated tubular element having a lubricous surface and formed of a polymer matrix and a lubricous fluid well dispersed within the matrix.

2. The intravascular catheter of claim 1 wherein the tubular element having a lubricous surface is an inner tubular member which is disposed within a second outer tubular member.

3. The intravascular catheter of claim 1 wherein the tubular element is an outer tubular member and has formed therein an inflatable element.

4. The intravascular catheter of claim 1 wherein the polymer matrix comprises thermoplastic, thermoset or elastomeric polymers or mixtures thereof.

5. The intravascular catheter of claim 1 wherein the lubricous fluid is a silicone oil.

6. The intravascular catheter of claim 5 wherein the lubricous fluid has a viscosity of about 300 to about 100,000 centipoise.

7. The intravascular catheter of claim 1 wherein the lubricous fluid has a viscosity of about 1000 to about 30,000 centipoise.

8. The intravascular catheter of claim 1 wherein the amount of lubricous fluid ranges from about 0.5 to about 20%.

9. The intravascular catheter of claim 1 wherein the amount of lubricous fluid ranges from about 1 to about 10%.

10. The intravascular catheter of claim 1 formed from a mixture of polymer, lubricous fluid and from about 0.01 to about 5% of a dispersing agent.

11. The intravascular catheter of claim 1 formed from a mixture of polymer, lubricous fluid and from about 0.05 to about 1% of a dispersing agent.

12. The intravascular catheter of claim wherein the dispersing agent is selected from the group consisting of lecithin, vegetable oil, polyethylene wax and mixtures thereof.

13. The intravascular catheter of claim 1 wherein the lubricous surface of the tubular element defines a short guidewire receiving inner lumen of a readily exchangeable dilatation catheter.

14. The intravascular catheter of claim 1 wherein the tubular element having a lubricous surface is an outer tubular element of a fixed-wire dilatation catheter.

15. The intravascular catheter of claim 2 wherein the tubular element having a lubricous surface has an inflatable member formed therein.

16. The intravascular catheter of claim 1 wherein the lubricous surface has a coefficient of friction from about 0.03 to about 0.2.

17. A composite material comprising a thermoplastic polymer matrix and a well dispersed lubricous fluid.

18. The composite material of claim 17 wherein the plastic matrix is formed of a biocompatible polymer material.

19. The composite material of claim 17 having a coefficient of friction from about 0.03 to about 0.2.

20. A balloon dilatation catheter comprising:

a) an elongated catheter shaft having an inner tubular member which is formed of a thermoplastic polymer matrix and a well dispersed lubricous fluid and which is provided with a guidewire receiving low friction inner lumen extending therein and an outer tubular member which is disposed about the inner tubular member and which defines with the inner tubular member an inflation lumen; and

b) an inflatable member on a distal portion of the catheter shaft

having an interior in fluid communication with the inflation lumen.

21. The balloon dilatation catheter of claim 20 wherein the lubricous fluid is a dimethylsiloxane polymer having a viscosity between about 300 and 100,000 centipoise.

22. A method of performing an angioplasty procedure on a patient comprising:

a) providing a dilatation catheter having,

an elongated catheter shaft which has an inner lumen extending therein and which is formed of a polymer matrix and a lubricous fluid well dispersed within the matrix, and

an inflatable member on a distal portion of the catheter shaft having an interior in fluid communication with the inner lumen extending within the catheter shaft;

b) advancing the dilatation catheter through the vasculature of the patient until the inflatable member is disposed within a stenosis to be dilated; and

c) directing inflation fluid through the inner lumen within the catheter shaft to the interior of the inflatable member to inflate the inflatable member and dilate the stenosis.

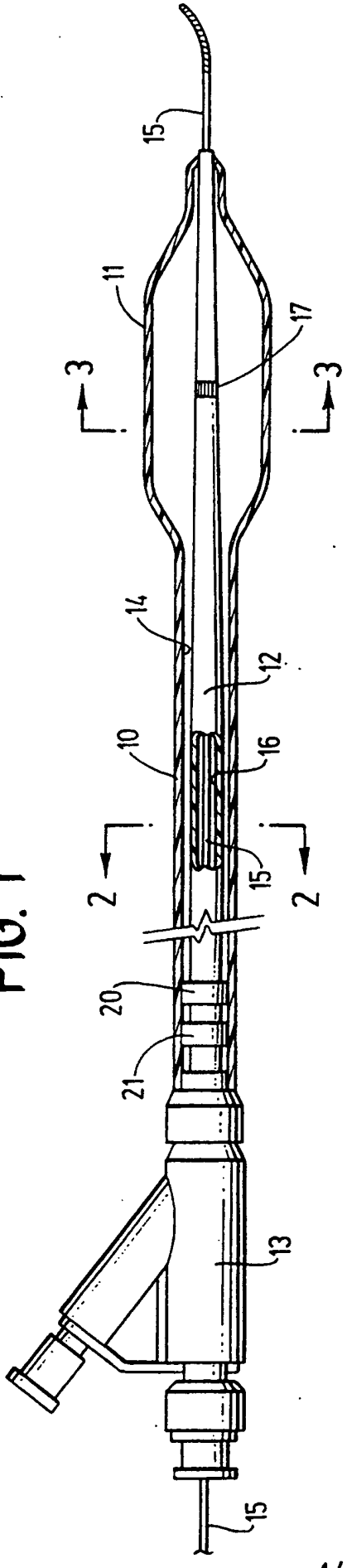

FIG. 1

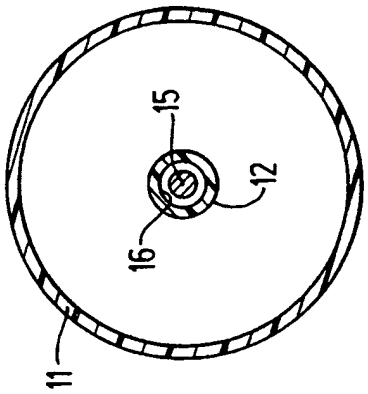

FIG. 3

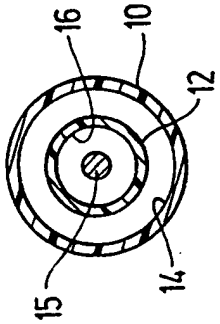

FIG. 2

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M25/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M ; A61L

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
A	EP,A,0 322 278 (SOCIETE NATIONALE DES POUDRES ET EXPLOSIFS) 28 June 1989 see abstract ---	1-21
A	US,A,4 838 876 (WONG ET AL.) 13 June 1989 see column 2, line 49 - line 56 ---	1-21
A	EP,A,0 380 102 (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 1 August 1990 see abstract; figures 1-2 ---	1-21
A	EP,A,0 279 959 (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 31 August 1988 see abstract; figures 1-4 -----	1-21

° Special categories of cited documents :[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
20 OCTOBER 1993	25. 10. 93
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/06054

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 22
because they relate to subject matter not required to be searched by this Authority, namely:
Method of performing an angioplasty procedure.
Please see Rule 39.1(iv) PCT.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

US 9306054
SA 76412

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0322278	28-06-89	FR-A- 2624868	23-06-89
		US-A- 4994203	19-02-91
		US-A- 5072672	17-12-91
US-A-4838876	13-06-89	None	
EP-A-0380102	01-08-90	CA-A- 2007743	26-07-90
		JP-A- 2289264	29-11-90
EP-A-0279959	31-08-88	AU-B- 620320	20-02-92
		AU-A- 1006788	07-07-88
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		JP-A- 63238859	04-10-88
		US-A- 4976720	11-12-90

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